01/22/2021

Corporate Summary

Overview

OyaGen has its origins in the science of gene editing enzymes that affect the genetic readout of cells and viruses, through the academic work of Dr. Harold C. Smith, University of Rochester, Rochester, NY (http:/dbb.urmc.rochester.edu/index.htm). Founded by Dr. Smith in 2003, OyaGen, Inc. holds exclusive Intellectual Property (IP) licensed from Thomas Jefferson University and numerous self-generated IP on the Company's platform of drug targets and antiviral lead compounds. In 2010 OyaGen began drug discovery work on oral deliverable anti viral compounds for HIV based on a novel viral drug target and methodology that distinguished the Company's approach from all others in the pharmaceutical space. We are the only commercial effort drugging the HIV Vif protein thereby enabling natural (innate) immunity through host cell restriction factors to effectively neutralize all clades and strains of HIV. Lead compounds under development have been tested and acknowledged for their potential as first-in-class drug candidates by the Federal Government (NIAID). In addition, the Company has a platform technology that has enabled advanced lead identification for SARS-CoV-2, MERS, Ebola and Lassa virus whose safety is known in human subjects and preclinical animal studies.

Coronavirus

OyaGen developed Oya1 in collaboration with NIH/NIAID as a highly potent compound that prevents the spread of infection of Coronaviruses, Ebola, Lassa virus and Pox virus. OyaGen is seeking FDA approval for its patent-protected Oya1 in the treatment of COVID-1 and have completed preIND discussions with the FDA. Oya1 is significantly more effective in stopping live SARS2 and Ebola virus infections in the laboratory than Gilead Sciences' Remdesivir® but in combination with Remdesivir®, markedly improved the antiviral efficacy of Remdesivir®; enabling maximal virus stopping power with lower doses for both drugs. Human safety has already been evaluated by the NCI in phase I and phase II clinical trials in the 1960s when Oya1 was evaluated as a candidate for cancer treatment. Oya1 had no serious adverse side effects in these studies when tested in 88 human subjects over a range of doses and dose intervals but was abandoned due to a lack of efficacy against various cancers. Oya1 is therefore a near term treatment solution addressing the unmet need for a highly effective medical countermeasure for people who become infected with SARS-CoV-2 and for immunocompromised patients who cannot benefit from COVID immunization.

Coronavirus (CoV) infections with higher than expected morbidity and mortality have emerged three times in the past two decades (SARS1, MERS and SARS2). Global biomedical science is only now racing to identify vaccines for what has now been predicted to be a disease with annual reoccurrence. COVID-19 vaccines have been developed but their global deployment has faced challenges and their efficacy and potential for establishing herd immunity is hotly debated. The international focus on COVID-19 vaccine development for prevention has left an unmet need for highly active, antiviral therapies for treating people who become infected and need highly active antiviral therapies to prevent disease progress, serious side effects or death. Laboratory testing performed in collaboration with NIAID suggested that Oya1 may be the most effective treatment for COVID-19 to date.

The data support that Oya1 alone or in combination with Remdesivir® (and potentially other treatment regimens including monoclonal antibodies (Mab), convalescent serum and/or corticosteroids or other immune modulators) holds the potential to halt COVID-19 and the now readily apparent threat from new viral strains that may have greater virulence or resistance to Mab therapeutics and current vaccines.

HIV and Ebola Market

HIV-1: OyaGen will soon complete IND-enabling studies and engage the FDA in preIND discussions for Irino-L, a patent-protected, first-in-class antagonist of the HIV-1 Vif protein that protects the APOBEC innate immune system and blocks HIV replication through gene editing. Formulation for oral dosing is the Company's priority. OyaGen has developed Irino-L through grants and contract research with NIAID and has a series of follow on

Vif antagonists in development. Irino-L not only has therapeutic potential but holds the potential to reduce viral reservoir formation as part of a strategy for a cure and prevention.

Irino-L and Vif antagonist will have significant market pentation because there remains a significant health care unmet need due to new infections and 30+ million HIV/AIDS patents worldwide. The drug market is expected to continue to show sustained growth despite advances in controlling the progress of the disease (Cowen & Company). The incidence of HIV continues to grow at a double-digit rate in developed markets according to the U.S. Center for Disease Control. Patient treatment remains low. Approximately 30% of US citizens infected with HIV are unaware they are HIV positive While treated patients have longer survival, the failure rates for current frontline therapies are 10% and ultimately the virus's ability to mutate continues to demand new drugs. Each first-in-class HIV drug has achieved blockbuster annual sales (Cowen & Co.). In recent years the Pharma pipeline for new class of HIV therapeutics have dried up largely due to reduction in R&D expenditure. OyaGen preclinical development for a first-in-class treatment is unique in the global effort has significant potential for treatment, prevention and cure.

Ebola: Oya1 originally was first discovered as broad microbicide and an Ebola antiviral in collaboration with NIAID. This work was recently published (Bennett *et a*l., (2021) **'**A Novel Ebola Virus VP40 Matrix Protein-Based Screening for Identification of Novel Candidate Medical Countermeasures**' Viruses** *Viruses 13* https://doi.org/10.3390) and is patent protected. The published data show that Oya1 is markedly more effective than Remdesivir® but has significant virus stopping capability alone or in combination with Remdesivir®.

Clinical trials showed that Mab therapy had greatest therapeutic value in treating Ebola. Vaccination strategies for Ebola and Remdesivir® were minimally effective for people infected with Ebola who already have symptoms. The unmet need is that protection through immunization takes 21 days but the virus kills in 14 days. When an Ebola vaccine becomes available, it may prevent the spread of Ebola to those who are immunized but it will not prevent transmission or death of persons within the disease epicenter who are not immune. Mab production and distribution are costly and require special infrastructure. OyaGen will address the unmet need for highly active antiviral therapies that are low in cost of production and distribution. OyaGen's lead is intended for oral or ballistic deliver for people who become infected.

OyaGen Key Assets

OyaGen has discovered and patented first-in-class lead (Irino-L) that enables our innate immunity against HIV as a treatment with curative potential for HIV/AIDS and patented best-in-class Oya1 as candidate treatment for infections due to Coronavirus, Ebola virus, Lassa virus and Pox virus. In addition, the Company's laboratory, platform technology and broad technical knowhow has enabled the development of a cancer drug discovery platform based on gene editing enzymes. There are more than 20 scientist working on the Company's projects through established contract research and co-development relationships with NIH/NIAID, Southern Research, ImQuest Biosciences, Cayman Chemical. These scientists support viral testing, medicinal chemistry, cGMP compound production. OyaGen works closely with regulatory consultants and clinical CROs. This team is accelerating the preclinical medicinal chemistry, ADME and safety testing needed for filing an IND for our HIV lead and the Coronavirus and Ebola antiviral lead.

Drs. Harold C. Smith, Founder and CEO, Ryan P. Bennett, CSO and Laboratory director and Jason D. Salter, Scientist, lead the Company's drug discovery and drug development efforts. The Company currently occupies a 3,200 sq. ft. state-of-the-art laboratory within the Rochester BioVenture Center in Rochester NY. A broad range of advanced instrumentation, controlled environments, small molecule libraries in a BLS2+ facility enable in-cell and cell-free assay development, infectivity and other functional endpoint analyses and high throughput screening at our current rate of 5,000 compounds/assay/day. We maintained a low overhead and sustainable footprint through association with contract laboratories, both federal and private, that perform specialized testing and validation services.

The Company has a management team and external advisors with collectively over 100 years of experience in Biopharma and the Life Sciences. Dr. David Ho, CEO of the Aaron Diamond AIDS Research Center at Rockefeller University (NYC) who was a Time Magazine Man of the Year and one of the world's leading HIV authorities serves on the Scientific Advisory Board (SAB). Dr. Roscoe Moore, former Assistant Surgeon General and OyaGen Board member advises the company on worldwide health priorities, Dr. James Cummings, president of ICON and Dr. Richard Ogden, former Agouron/Pfizer scientist and executive. OyaGen's Board

member advises the company on pharmaceutical industry trends. Amy Fix, MS. MBA, RAC and VP of regulatory affairs with Arcellx, Inc serves as the company's regulatory consultant, Thomas Fitzgerald, Esq serve as Chief Operations Officer and legal consultant; Andrew Gonsalves, Esq with FisherBroyles serves as patent attorney consultant and Kimberly Staffieri, financial and controller services.

OyaGen maintains an informative website that provides more detailed information about HIV and the approach that the Company used to advance its range of therapeutics. (http://www.oyageninc.com) with two medical animations describing the HIV therapeutic and cure approaches (searchable in YouTube under Oyageninc). The Company also has a Wikipedia page and is on Facebook.

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Nonconfidential

OyaGen Presents a Novel Treatment Candidate for COVID-19

- **OyaGen, Inc is an upstate NY biotech company that has in developed Oya1, a highly potent and cost effective antiviral therapeutic for COVID-19 with intended use in the treatment for patients with an active COVID-19 infection.**

- **Oya1 will address the unmet need for an effective countermeasure to fill the gaps where vaccines do not have an immediate benefit for patients who are already infected or are immune-compromised.**

- **Combined treatments of Oya1 and remdesivir or monoclonal antibodies are anticipated to markedly enhance therapeutic efficacy while mitigating the emergence of drug resistant CoV.**
  - NIH/NCI has shown Oya1 to be safe across a range of doses and dose intervals when tested in humans enrolled in prior cancer clinical trials.
  - Oya1 low nanomolar antiviral efficacy has been third party validated by NIH/NIAID.
  - Oya1 has an average selectivity index $\geq$ 14 when tested in different cell types.
  - Maximum tolerated doses are known for rodents, dogs and African green monkeys.
  - NIH/NIAID has shown that Oya1 blocks the virus from making copies of itself. It does so at low and high virus levels and even when added before or after the virus enters cells.

- **COVID-19 therapeutics that include Oya1 will be a game changer.**
  - Oya1 $\geq$30-times more effective against live SARS-CoV-2 than Gilead Science's remdesivir in laboratory tests.
  - Oya1 and remdesivir have additive antiviral effects and when combined, reduce the amount of total drug necessary to kill the virus.
  - Mab require specialized lab resources for their production. They are biologics that are very expensive to produce and may require special storage conditions.
  - Oya1 has an inexpensive five step synthesis, has a long shelf-life, and does not require special considerations for storage or shipment; addressing a global demand for therapeutic options.

- **There is an immediate and long-term demand for Oya1 regardless of the availability of vaccines or monoclonal antibodies (Mab) therapies.**
  - Vaccines are not therapeutic; alone they are not indicated for reducing active COVID disease because of the time it takes to mount an immune response.
  - COVID vaccines could be given to 'sick' people in combination with potent and fast acting therapeutics such as Oya1 that do not depend on an immune response.
  - While Mab treatments are intended for treating infected patients, like vaccines, they may only be effective for the current strain of CoV (e.g. Flu vaccines).
  - Combined modality therapeutics also are required to suppress emergence of therapeutic resistant CoV strains selected by monotherapy with remdesivir or Mab.

- **Pre-IND discussions with the FDA have confirmed studies that will gate the entry of Oya1 for human Phase I clinical trials.**

- **The company seeks to partner or license Oya1 or obtain a tranched capital raise enabling OyaGen to complete remaining preclinical studies required by the FDA for approval of an IND and Phase I clinical safety and pharmacokinetic studies.**

Nonconfidential

OyaGen Presents a Novel Treatment Candidate for HIV

- **OyaGen, Inc is an upstate NY biotech company that has developed Irino-L, a highly potent antiviral therapeutic for a novel HIV target with intended use in treatment for patients with an HIV infection as part of a therapeutic and/or cure strategy and for pre-exposure prophylaxis (PrEP).**
- **Irino-L is a prodrug whose active metabolite SN38-L blocks Vif mediated destruction of APOBEC3 (A3) proteins that otherwise would serve in innate immunity against HIV.**
  - A3 proteins prevent the spread of HIV infection by inducing catastrophic mutations in the viral genetic code.
  - In the absence of SN38-L, Vif binds to A3 proteins and induces their destruction.
  - SN38-L has a low nanomolar efficacy and an average selectivity index $\geq$ 185 when tested in PBMCs against multiple viral subtypes.
  - The prodrug strategy enables antiviral levels of SN38-L to be maintained for 24 hours with twice daily dosing.
  - In vitro ADMET and PK analyses for Irino-L, SN38-L and an analog with similar activity, O5-SN, have been completed and show a clear path for formulation of the drug for human clinical trials.
- **Irino-L is the lactam analog of Irinotecan derived from camptothecin. Irinotecan is a chemotherapy that is safely used in humans as a standard of care for multiple cancer types and has been shown to be safe across a range of doses and dose intervals.**
  - Studies conducted by OyaGen and in the literature show that lactam analogs of camptothecin such as Irino-L no longer inhibit the cancer target for Irinotecan, Topoisomerase I and therefore have no cellular off-target effects and lower cytotoxicity by comparison.
- **HIV therapeutic and cure strategies that include Irino-L will be a game changer.**
  - Combined treatments of Irino-L and antiretroviral (ARV) drugs are anticipated to markedly enhance therapeutic efficacy, reduce the total amount of ARV required to suppress viremia and will help to mitigate the emergence of drug resistant HIV. Viral resistance studies showed that HIV did not develop resistance to SN38-L in human white blood cells presumably arising from Vif function in A3 degradation requiring several interactions with A3 and other host cellular proteins.
- **Irino-L treatment in combination with latent virus activation may lead to a functional cure.**
- **OyaGen's APOBEC platform technology holds promise for the discovery of first-in-class drug leads for other antiviral therapeutics and anti-cancer therapeutics.**

The company seeks to partner or license Irino-L or obtain a tranched capital raise enabling OyaGen to complete remaining preclinical studies to determine the optimal formulation in order to complete animal safety studies required by the FDA for approval of an IND and initiation of Phase I/IIA clinical studies.

Nonconfidential

OyaGen Presents a Novel Treatment Candidate for Ebola

- **OyaGen, Inc is an upstate NY biotech company that has in developed Oya1, a highly potent and cost effective antiviral therapeutic for Ebola with intended use in the treatment for patients with an active Ebola infection.**

- **Oya1 will address the unmet need for an effective countermeasure to fill the gaps where vaccines do not have an immediate benefit for patients who are already infected or are immune-compromised.**

- **Combined treatments of Oya1 and remdesivir or monoclonal antibodies are anticipated to markedly enhance therapeutic efficacy while mitigating the emergence of drug resistant Ebola.**
  - Oya1 low nanomolar antiviral efficacy has been third party validated by NIH/NIAID.
  - NIH/NIAID has shown that Oya1 blocks the virus from making copies of itself. It does so at low and high virus levels and even when added before or after the virus enters cells.
  - Oya1 has a selectivity index $\geq$ 10 when tested in different cell types.
  - NIH/NCI has shown that Oya1 can be safely administered across a range of doses and dose intervals when tested in humans enrolled in prior cancer clinical trials.
  - Maximum tolerated doses are known for rodents, dogs and African green monkeys.

- **Ebola therapeutics that include Oya1 will be a game changer.**
  - Oya1 $\geq$30-times more effective against live than Gilead Science's remdesivir in laboratory tests.
  - Oya1 and remdesivir have additive antiviral effects and together reduced the amount of total drug necessary to kill the virus.
  - Combined modality therapeutics will suppress emergence of drug resistant Ebola strains.

- **There is an immediate and long-term demand for Oya1 regardless of the availability of vaccines or monoclonal antibody (Mab) therapies.**
  - Vaccines are not therapeutic; they alone are not effective in reducing active disease in people who already have Ebola because of the time it takes to mount an immune response. All vaccines could be given to 'sick' people in combination with a fast acting therapeutics such as Oya1 that do not depend on an immune response.
  - While Mab treatments are intended for treating infected patients, like vaccines, they may only be effective for the current strain of Ebola (e.g. Flu vaccines).
  - Mab require specialized lab resources for their production. They are biologics that are very expensive to produce and may require special storage conditions.
  - Oya1 has an inexpensive five step synthesis, has a long shelf-life, and does not require special considerations for storage or shipment.

- **Pre-IND discussions with the FDA have confirmed studies that will gate the entry of Oya1 for human Phase I clinical trials.**

- **The company seeks to partner or license Oya1 or obtain a tranched capital raise enabling OyaGen to complete remaining preclinical studies required by the FDA for approval of an IND and Phase I clinical safety and pharmacokinetic studies.**

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OyaGen's Platform of APOBEC Enzymes in Oncology

- **OyaGen, Inc is an upstate NY biotech company that has a discovery stage hit-to-lead oncology program for the identification and development of treatments that will reduce cancer progression.**

- **Cellular proteins known as AID, APOBEC3A, APOBEC3B are gene editing enzymes that become misregulated in various cancers to cause chromosomal mutations that drive the development and progression in several types cancer.**
  - OyaGen's CEO is a founder and thought leader on APOBEC RNA and DNA editing enzymes and has contributed over 120 peer-review scientific papers in the past 30 years
  - OyaGen is recognized nationally and internationally for its platform of drug discovery methods and reagents on the APOBEC enzymes using support in grants from NIH, The Bill and Melinda Gates foundation and equity investment

- **Drugs that inhibit APOBEC enzymes will address unmet needs in mitigating cancer risk and cancer progression that are characteristic of B cell lymphoma and leukemia, breast cancer, colorectal cancer, head and neck cancer, hepatocellular carcinoma, stomach cancer, metastatic disease, non-small cell lung cancer and ovarian cancer.**
  - Disease progress in a variety of cancers is widely recognized as driven by unregulated and off-target mutagenic activity by APOBEC enzymes on chromosomal DNA and yet this fundamental cancer mechanism remains an unmet need in drug discovery
  - OyaGen's unique high throughput assay for inhibitors of AID gene editing activity has been third part validated in identifying compounds that are selective inhibitors of the pathway AID uses to enter the cell nucleus and access chromosomal DNA
  - Other high throughput assays that seek inhibitors APOBEC3A and APOBEC3B gene mutation activity are in concept and development stages
  - OyaGen has a platform of cell and molecular methods that will enable and validate hits from its oncology drug discovery campaign and accelerate hit-to-lead optimization and IND-enabling studies
- **OyaGen is uniquely positioned to deliver high impact in novel cancer therapeutics.**
  - Innovative new cancer therapies are in high demand
  - OyaGen's therapeutics currently have no competition
  - Unique opportunity to establish a patent estate.
  - OyaGen anticipates that the leads produced by the company will be disruptive in the industry and that these leads will be patented as first-in-class therapeutics for cancer
- **Pre-IND discussions with the FDA are anticipated in 2022 assuming sufficient funding.**
- **The company seeks to partner or license Oya1 or obtain a tranched capital raise enabling OyaGen to fully develop and pursue novel cancer treatments that are anticipated to prevent tumor progress, reduce cancer risk and save lives.**